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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,824	09/23/2003	Cai-Zhong Jiang		2629

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Mendel Biotechnology, Inc.
3935 Point Eden Way
Hayward, CA 94545-3720

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,824	JIANG ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2010 and 26 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,25-27,30-33,36-38 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43,44,49 and 51 is/are allowed.
- 6) ☒ Claim(s) 22,25-27,30-33,36-38,41,42,45-48 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 April 2010 has been entered.
2. The claims amendment filed 25 March 2010 has been entered.
3. This Office action is in response to the Amendment and Remarks filed on 25 March 2010.
4. The rejection under 35 U.S.C. § 112, first paragraph, for lack of scope of enablement is withdrawn in view of Applicants' amendments.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 22, 25-27, 30-33, 36-38, 41, 42 and 45-48 remain rejected and claim 50 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 25 November 2009. Applicant's arguments filed 25 March 2010 have been fully considered but they are not persuasive.

Applicants argue that the claimed sequences all belong to the AT-hook transcription factor family, and have at least a conserved AT hook domain and the second conserved domain as described. Applicants argue that it is well-known that conserved domains are art-recognized as important and distinct functional and structural units of a protein. Applicants argue that "The independent evolutionary histories of domains found within the same protein lead to an assumption that the domain is the fundamental unit of protein structure and function" (Doerks 2002 *Genome Res.* 12, attached, page 47, column 1), and "Conserved protein domains are most useful when they can be used to make predictions of likely function" (*Id.*, page 49, column 2), and "On the basis of reports in the literature and/or co-occurrence with previously identified domains, some functional features can be predicted for 78.6% of our newly identified set of 28 domain families. Applicants argue that this represents an increase in the state of functional prediction for approximately 700 proteins (i.e., the total number of distinct proteins that are covered by novel domains with a putative function (page 53, column 2) (paragraph spanning pages 6-7 of the Remarks). These arguments are not found to be persuasive. Doerks teaches that proteins comprising an AT_Hook could be predicted to have "DNA-binding" function or "Metal binding" (page 49, Table 1). This is not a description of a predictable specific function.

Applicants argue that the second conserved domain, referred to as a domain with unknown function (page 27), comprises almost all of the art-recognized DUF296 domain by conserved domain analysis using methods provided at www.ncbi.nlm.nih.gov. Applicants argue that Alves et al. 2009 (submitted to the Office with the previous response) also noted that DUF296 is a domain of unknown function that contains what appears to be a zinc finger like motif, which suggests that these proteins may be involved in DNA binding, probably acting in regulation of gene expression (the second paragraph at page 10 of Alves et al., 2009, *supra*). Applicants argue that Richardt et al., 2007 (submitted to the Office with the previous response) also recognized that "PT007 might represent a novel TF family is fortified by the domain structure of the members, most of which contain the two PFAM domains AT hook (PF02178) ... and DUF296 (PF03479), which are known to be present in this particular order in a class of proteins that is thought to have DNA-binding activity" (column 2, page 1459 of Richardt et al., 2007, *supra*). Applicants argue that Richardt also cited Weigel et al., 2000 in which overexpression of a protein containing DUF296 has been shown to lead to late flowering and modified leaf development in *Arabidopsis* (column 2, page 1459 of Richardt et al., 2007, *supra*) (paragraph spanning pages 7-8 of the Remarks). These arguments are not found to be persuasive. The instant claims have been given the priority date of 23 September 2003 as stated in the Office action mailed on 8 July 2007. The teachings of Alves *et al* 2009 would not support Applicants' assertions. As stated above, DNA binding is not a specific functional description.

Applicants argue that they have provided at least seventeen examples highly homologous to SEQ ID NO: 14 and have the AT hook domain and the second conserved domain that are highly homologous to amino acids 62-70 and 106-201 of instant SEQ ID NO: 14 (page 8, 2nd paragraph of the Remarks). The conserved domain (claim 22) represents only 34% of instant SEQ ID NO: 14. Applicants do not provide evidence that this "conserved domain" in association with an AT hook domain describes a transcription factor that "when over-expressed in a transgenic plant confers to the transgenic plant greater drought tolerance or greater biomass relative to a control plant". Applicants have disclosed a soy sequence G3456 (SEQ ID NO: 14), two *Arabidopsis* sequences G1069 (SEQ ID NO: 42) and G2153 (SEQ ID NO: 6) and a rice sequence G3401 (SEQ ID NO: 38); these sequence share 100%, 60.4%, 66.1% and 61.5% sequence identity with SEQ ID NO: 14, respectively. These sequences only describe the extremes of the claimed genus, not a representative number of species that describe the variation within the genus.

Applicants' arguments concerning Example 9 of the USPTO Synopsis of application of written description guidelines are not found to be persuasive (paragraph spanning pages 8-9 of the Remarks). Applicants do not describe a specific structure that produces the claimed specific function; "when over-expressed in a transgenic plant confers to the transgenic plant greater drought tolerance or greater biomass relative to a control plant".

Applicants argue that they have disclosed numerous representative sequences from diverse plant species, which have two conserved domains and are at least 50%

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identical to SEQ ID NO: 14. Applicants argue that they have additionally disclosed sufficient relevant identifying structure elements of the claimed genus, i.e. the AT hook motif and the second conserved domain that are highly homologous to those present in G3456, SEQ ID NO: 14, and also functional characteristics, i.e. conferring drought tolerance or greater biomass, coupled with a disclosed and art-recognized correlation between the structure and function (page 9, 3rd paragraph of the Remarks). These arguments are not found to be persuasive. As stated above, Applicants have not described the variations within the claimed genus. At instant claims 25, 30, 36, 41, 45-48 and 50, Applicants only describe a single species within the claimed genus (see also Applicants arguments on page 11 of the Remarks).

Applicants argue that there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure, citing *Falkner v. Inglis* 79 USPQ2d 1001. Fed. Circ. 2006 (page 12 of the Remarks). These arguments are not found to be persuasive because in the case of *Falkner v. Inglis*, it was found that it was accessible literature sources that had adequately describe the structural feature encompassed by the senior parties' claim. See *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co.*, 94 USPQ2d 1161 (Fed. Cir. 2010) which states that "There are, however, a few broad principles that hold true across all cases. We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 [79 USPQ2d

1001] (Fed. Cir. 2006). Conversely, we have repeatedly stated that actual “possession” or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 [88 USPQ2d 1233] (Fed. Cir. 2008), or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement, *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 [41 USPQ2d 1961] (Fed. Cir. 1997)”.

Applicants’ arguments concerning Example 11B of the Written Description Training Materials Revision 1, March 25, 2008 are not found to be persuasive (paragraph spanning pages 12-13 of the Remarks). First, the AT-hook domain is a non-specific structure as it relates to a specific structure that produces the claimed specific function; "when over-expressed in a transgenic plant confers to the transgenic plant greater drought tolerance or greater biomass relative to a control plant". The conserved domain that is at least 65% identical to amino acids 106-201 of SEQ ID NO: 14 is not describe in the specification, or the prior art, as a specific structure that produces the claimed specific function; "when over-expressed in a transgenic plant confers to the transgenic plant greater drought tolerance or greater biomass relative to a control plant".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 22, 26-27, 31-33, 37-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin, X (NCBI Accession No. AAF04888, Online, NIH, National Library of Medicine, Bethesda, MD USA; publicly disclosed on 2 November 1999), in view of Lamb *et al* (U.S. Patent 5,834,236).

Lin teaches an AT hook transcription factor polypeptide, and polynucleotides encoding same, that comprises a conserved domain that is 80.2% identical to amino acids 106-201 of instant SEQ ID NO: 14. Lin teaches Applicants' SEQ ID NO: 6.

Lin does not teach transgenic plants or methods of making explicitly.

Lamb *et al* teach making a recombinant construct comprising a polynucleotide encoding an HMG I/Y, AT-hook transcription factor operably linked to a constitutive or inducible promoter at claims 4, 5 and 6. Lamb *et al* making a transgenic plant using said recombinant construct at claim 4.

It would have been *prima face* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Lin to make a transgenic plant transformed with a recombinant construct encoding the AT hook transcription factor using the teachings of Lamb *et al*. Given the teachings of Lamb *et al*, one of ordinary skill in the art would have had a reasonable expectation of success. This rejection is made because the Office's search shows Applicants' SEQ ID NO: 6 to be 56.2% identical to Applicants' SEQ ID NO: 14 as shown in the Office action attachment. Instant claims 32 and 33 are deemed obvious because the recited method steps would have

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been considered obvious; growing a transgenic plant cell in to a transgenic plant is obvious in view of the teachings of Lamb *et al.*

This rejection has been modified from that of the Office action mailed on 25 November 2009 to address Applicants' arguments concerning the teachings of Sawa *et al.* The Examiner addresses Applicants' arguments concerning the teachings of Lamb *et al.*

Applicants argue that Lin's NCBI submission described AAF04999 as a "hypothetical protein" and provided "no additional details recorded". Applicants argue that without any real world utility, one of ordinary skill in the art would not have even considered making a recombinant construct and introducing this sequence into plant (page 17 of the Remarks).

Applicants argue that The Supreme Court has "warn[ed] against 'temptation to read into the prior art the teachings of the invention in issue' and instruct[ed] courts to 'guard against slipping into the use of hindsight.'" *KSR Int'l v. Teleflex Inc.*, 127 S.Ct 1742 (2007), quoting *Graham v. John Deere Co.*, 383 U.S. at 36. Applicants argue that the presently amended claims are now limited to the recombinant constructs, transgenic plants and methods to make such plants that over-express polypeptides that are closely related to SEQ ID NO: 14 (including SEQ ID NO: 6) and can confer more drought tolerance or increased biomass relative to control plants. Applicants argue that The Supreme Court in KSR has emphasized its focus on obviousness of combinations of known components: "A patent composed of several elements is not proved obvious merely by demonstrating that each element was independently known in the art" and

"[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". (Id. at 1739), and "[w]hen a patent simply arranges old elements with each performing *the same function it had been known to perform*, and yields no more than one would expect from such an arrangement, the combination is obvious". Id. (quoting *Sakraida v. AG Pro, Inc.* 425 U.S. 273, 282 (1976), *emphasis added*) (page 18 of the Remarks).

Applicants argue that recombinant constructs, plant cells or plants transformed with the polynucleotide of SEQ ID NO: 6 have never existed before the claimed invention, and that Lin's NCBI submission has predicted the instant results, or teaches a "function it had been known to perform", i.e. conferring increased biomass or more drought tolerance by overexpressing SEQ ID NO: 6 in plants (paragraph spanning pages 18-19 of the Remarks).

Applicants argue that neither the references alone or in combination teach or suggested that over-expression of the claimed sequences in plants will result in greater biomass or greater drought tolerance. Applicants argue that both the recombinant constructs and the transgenic plants are unobvious in view of the cited prior arts as discussed above, and they constitute material limitations to the claimed methods; the claimed method steps could not be completed without the novel constructs and transgenic plants (page 19, last paragraph of the Remarks).

Applicants' arguments are not found to be persuasive. In the instant art it is standard practice to introduce an identified open reading frame identified in a plant's genome to transform a plant to identify its function. In the instant art it is most obvious to

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either overexpress the identified open reading frame in a transgenic plant or to produce a knockout mutant in the homologous plant, hence there would have been a *prima face* limited number of options obvious to one of ordinary skill in the art at the time of Applicants' invention. Lin *et al* had taught a recombinant construct that being a BAC (bacterial artificial chromosome) comprising a polynucleotide encoding instant SEQ ID NO: 6. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Applicants' arguments concerning the results of the overexpression of instant SEQ ID NO: 6 in a plant are not found to be fully persuasive because the function of instant SEQ ID NO: 6 overexpressed in a transgenic plant would naturally flow from the structure of instant SEQ ID NO: 6.

Conclusion

9. Claims 43, 44, 49 and 51 are allowed.
10. Claims 22, 25-27, 30-33, 36-38, 41, 42, 45-48 and 50 are rejected.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
4 January 2011